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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/943,777	10/03/97	STENDER	H

EXAMINER	
FREDMAN, J	
ART UNIT	PAPER NUMBER
1655	22

DATE MAILED: 06/21/01

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HM22/0621

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
08/943,777	Stender et al
Examiner	**Art Unit**
Jeffrey Fredman	1655

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *three* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) [X] Responsive to communication(s) filed on *May 14, 2001*.

2a) [ ] This action is **FINAL**. 2b) [X] This action is non-final.

3) [ ] Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) [X] Claim(s) *1-36* is/are pending in the application.

4a) Of the above, claim(s) *1-24, 35, and 36* is/are withdrawn from consideration.

5) [ ] Claim(s) _____ is/are allowed.

6) [X] Claim(s) *25-34* is/are rejected.

7) [ ] Claim(s) _____ is/are objected to.

8) [ ] Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) [ ] The specification is objected to by the Examiner.

10) [ ] The drawing(s) filed on _____ is/are objected to by the Examiner.

11) [ ] The proposed drawing correction filed on _____ is: a) [ ] approved b) [ ] disapproved.

12) [ ] The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) [X] Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) [ ] All b) [ ] Some* c) [X] None of:

1. [X] Certified copies of the priority documents have been received.
2. [ ] Certified copies of the priority documents have been received in Application No. _____.
3. [ ] Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) [ ] Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) [X] Notice of References Cited (PTO-892)

16) [ ] Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) [X] Information Disclosure Statement(s) (PTO-1449) Paper No(s). *5,6*

18) [X] Interview Summary (PTO-413) Paper No(s). *22*

19) [ ] Notice of Informal Patent Application (PTO-152)

20) [ ] Other:

DETAILED ACTION

Election/Restriction

1. Applicant requested that the previous election be vacated and that a new election of Group II, claims 25-34 be made. The examiner will permit this shift, but notes that those claims were accidentally abandoned. As discussed in the interview on June 19, 2001, the examiner will treat claims 25-34 as if they were reintroduced by the response of May 14, 2001. Applicant is requested to enter the claims (or better yet, amended claims to reflect this action).

Sequence Rules

2. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reasons of record. Applicant is requested to comply with the sequence rules.

Claim Rejections - 35 USC § 101

3. Claims 25-27 provide for the use of peptide nucleic acids, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 25-27 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for

example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 112

4. Claims 25-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is vague and indefinite what is meant by the phrase "probe being capable of hybridising" in claims 1-4. The phrase "capable of" renders the claims indefinite because the capacity of a probe to perform some function is merely a latent characteristic of the probe and this language carries no patentable weight. See MPEP § 2173.05(b).

Regarding claims 26 and 27 and later claims, the phrase "in particular" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was

commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 25-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hogan et al (U.S. Patent 5,541,308) in view of Shah et al (U.S. Patent 5, 521,300) and further in view of Britschgi et al (U.S. Patent 5,726,021), and further in view of Hyldig-Nielsen et al (WO 95/32305).

Hogan teaches a method for detecting a mycobacterium target sequence (column 2) comprising: (1) contacting rRNA or rDNA in a sample with a nucleic acid probe, which probes comprise SEQ ID NO: 25 (see column 24, line 21) and SEQ ID NO: 34 (see column 18, line 20) under conditions whereby hybridization takes place between said probe and said rRNA or rDNA (column 2 to column 3), (2) observing or measuring detectable hybrids and relating the observation or measurement to the presence of a target sequence of mycobacteria (column 2 to column 3). Hogan expressly teaches detection of mycobacterium tuberculosis (column 2, line 47) as well as other orgasnims such as intracellulare, and avium (column 2, lines 40-42). Hogan further teaches in vitro, in situ hybridization (column 1) as well as the use of a variety of samples such as sputum (column 66, line 53). Hogan further teaches signal amplifying systems such as enzymes or other non-isotopic labels (column 11).

Hogan does not teach all of the sequences elected, nor does Hogan teach the use of PNA probes.

Shah teaches probe for detecting a mycobacterial target sequence which probes comprise SEQ ID NO: 8 (see column 93, SEQ ID NO: 72) and SEQ ID NO: 85 (see column 77, SEQ ID NO: 35)

Britschgi teaches probe for detecting a mycobacterial target sequence which probes comprise SEQ ID NO: 123 (see column 71, SEQ ID NO: 83).

Neither Shah or Britschgi teach the use of PNA backbones in oligonucleotide probes.

Hyldig-Nielsen teaches the use of PNA backbones, including a backbone of the formula of claims 6, 15 and 18 (see page 17 of Hyldig-Nielsen) in probes for the detection of microorganisms using 16S rRNA base compositions (abstract). Hyldig-Nielsen expressly teaches that Z is NH, R2 is H, R3 is H, R4 is H, X and Y are O and Q is a nucleobase on page 17. Hyldig-Nielsen further teaches the use of labels and solid phase hybridization systems (page 3 and page 17). Hyldig-Nielsen further teaches the use of kits, which incorporate solid phase capture systems (page 45).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to utilize the PNA backbone of Hyldig-Nielsen in the hybridization method of Hogan in view of Shah and further in view of Britschgi since Hyldig-Nielsen teaches that

> "The present PNA probes form complexes with complementary nucleic acids which complexes are considerably more stable (higher Tm value) than would be a similar hybrid formed by a typically used nucleic acid probe of

> corresponding sequence allowing sensitive assays to be made with shorter probes than is the case of typical nucleic acid probes used today. Hybridization with traditionally used nucleic acid probes is much faster in solution than in solid phase hybridization. Due to the high affinity of PNA for nucleic acid, even solid phase hybridization between PNA probes and nucleic acid can be performed rapidly allowing greater flexibility in assay format. Hybridization efficiency is only slightly influenced by pH and salt concentration in the hybridiation solution allowing PNAs to hybridize under conditions not favourable for ordinary DNA probes. Furthermore, PNAs have a higher thermal instability of mismatching bases wehreby PNAs exhibit a greater specificity for their complementary nucleic acids than traditionally used nucleic acid probes of corresponding sequence would do (ref omitted). The structure of PNA is not degraded by nucleases or proteases making the PNA molecular very stable in biological solutions (page 3, line 21 to page 4, line 7)".

An ordinary practitioner would have been abundantly motivated to utilize the PNA backbone in the mycobacterial probes of method of Hogan in view of Shah and further in view of Britschgi in order to gain the advantages of improved stability, increased specificity, increased speed of hybridization, increased assay format flexibility, and improved resistance to nucleases.

Allowable Subject Matter

7. Claims drawn to methods using PNAs comprising SEQ ID Nos: 40, 44, 76, 89 and 90 would be novel and unobvious over the cited prior art. Of course, the claims would be rewritten to overcome the 112, second paragraph rejections.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeff Fredman, Ph.D. whose telephone number is (703) 308-6568.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703) 308-1152.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission via the P.T.O. Fax Center located in Crystal Mall 1. The CM1 Fax Center numbers for Technology Center 1600 are either (703) 305-3014 or (703) 308-4242. Please note that the faxing of such papers must conform with the Notice to Comply published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Jeffrey Fredman
Primary Patent Examiner
Art Unit 1655

June 19, 2001